DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 5, 2016

SIMEX Medizintechnik, GmbH
Mr. Hamid Khosrowshahi
FloSure Technologies LLC
PO Box 123
Tarrytown, New York 10591

Re: K150459
Trade/Device Name: FloSure Ventilation Patch
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 3, 2015
Received: December 7, 2015

Dear Mr. Khosrowshahi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150459

Device Name
FloSure Ventilation Patch

Indications for Use *(Describe)*
The FloSure Ventilation Patch is intended to be used in conjunction with NPWT Dressing Kits compatible with the SIMEX NPWT Systems EX200 and EX300 for the application of negative pressure wound therapy to the wound. The FloSure Ventilation Patch is to be applied to the occlusive wound dressing. When used in conjunction with the Simex NPWT EX200 and EX300 pumps and dressing kits, the FloSure Ventilation Patch is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of wound exudates, infectious material and tissue debris.

The FloSure Ventilation Patch is appropriate for use on the following wounds:
- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-Operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Date Prepared:	January 2, 2016
Sponsor and Manufacturer:	SIMEX Medizintechnik, GmbH Post Box 1207 D-78649 Deisslingen, Germany FDA Registration Number 3005813597
510(k) Contact:	Mr. Hamid Khosrowshahi FloSure Technologies LLC PO Box 123 Tarrytown, NY 10591 Telephone: 914-772-7326 e-mail: hkhosrow@optonline.net
Trade Name:	FloSure Ventilation Patch
Common Name:	Occlusive Wound Dressing
Classification:	Powered Suction Pump 21 CFR 878.4780 Class II
Device Product Code:	OMP - Pump, Portable, Aspiration (manual or powered)
Predicate Device:	UNI NPWT Foam Wound Dressing Kit (K133333)

Indications for Use:

The FloSure Ventilation Patch is intended to be used in conjunction with NPWT Dressing Kits compatible with the SIMEX NPWT Systems EX^{200} and EX^{300} for the application of negative pressure wound therapy to the wound. The FloSure Ventilation Patch is to be applied to the occlusive wound dressing. When used in conjunction with the Simex NPWT EX^{200} and EX^{300} pumps and dressing kits, the FloSure Ventilation Patch is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of wound exudates, infectious material and tissue debris.

The FloSure Ventilation Patch is appropriate for use on the following wounds:
- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-Operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

Device Description:

The FloSure Ventilation Patch is used with the NPWT wound dressings to improve air-flow through the dressing when desired. The FloSure Ventilation Patch augments the transparent dressing by providing additional gas permeability to the wound dressing site through its

proprietary hydrophobic and micro-porous filter membrane. The access to additional air-flow can aid in keeping the vacuum in balance resulting in a continuous flow of exudate. Stagnation in the flow of exudate can cause pooling at the wound site and result in blockage alarms.

Technical Characteristics:

Feature Comparison Chart

Feature	FloSure Ventilation Patch	UNI NPWT Foam Wound Dressing Kit K133333
Product Name	FloSure Ventilation Patch	UNI NPWT Foam Wound Dressing Kits
Product Code	OMP	OMP
Description	Accessory for use with occlusive dressings to allow filtered air to flow through the occlusive dressing when desired. Used with SIMEX Negative Pressure Wound Therapy Systems (EX^{200} and EX^{300})	Foam based dressing including an occlusive drape to create a sealed wound environment Used with SIMEX Negative Pressure Wound Therapy Systems (EX^{200} and EX^{300})
Sterility	Provided Sterile	Provided Sterile
Mode of operation	The FloSure Ventilation Patch is applied to the occlusive (transparent) drape of the NPWT wound dressing. It maintains the moist environment of the NPWT dressing and allows the exchange of gases through a hydrophobic micro-porous filter membrane.	The occlusive drape of the wound dressing kit provides a moist wound environment, and allows the exchange of gases through the device.
Materials	Consists of a piece of synthetic polymeric material with an adhesive backing.	Occlusive drape consists of a piece of synthetic polymeric material with an adhesive backing.
Indications for Use	The FloSure Ventilation Patch is intended to be used in conjunction with NPWT Dressing Kits compatible with the SIMEX NPWT Systems EX^{200} and EX^{300} for the application of negative pressure wound therapy to the wound. The FloSure Ventilation Patch is to be applied to the occlusive wound dressing. When used in conjunction with the Simex NPWT EX^{200} and EX^{300} pumps and dressing kits, the FloSure Ventilation Patch is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of wound exudates, infectious material and tissue debris. The FloSure Ventilation Patch is appropriate for use on the following wounds: • Pressure Ulcers • Diabetic/Neuropathic Ulcers • Venous Insufficiency Ulcers • Traumatic Wounds • Post-Operative and Dehisced Surgical Wounds • Skin Flap and Grafts	The UNI NPWT Foam Dressing Kit is intended to be used in conjunction with the SIMEX Negative Pressure Wound Therapy Pumps (K113291) for the application of negative pressure wound therapy to the wound. When used in conjunction with the SIMEX Negative Pressure Wound Therapy Pumps, the UNI NPWT Foam Dressing Kit is indicated for patients who would benefit form a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris. The UNI NPWT Foam Dressing Kit is appropriate for use on the following wounds: • Pressure Ulcers • Diabetic/Neuropathic Ulcers • Venous Insufficiency Ulcers • Traumatic Wounds • Post-Operative and Dehisced Surgical Wounds • Skin Flap and Grafts

Non-clinical Testing:

The following non-clinical testing was performed:

- Cytotoxicity
- Sensitization
- Acute Systemic Toxicity
- Intracutaneous Reactivity or Irritation

Comparative performance bench testing was performed with the predicate and with the FloSure Ventilation Patch using the SIMEX EX^{200} and EX^{300} NPWT systems. Testing demonstrated equivalence in ability to maintain consistent pressure, flow and removal of exudate and demonstrated that the FloSure Ventilation patch did not interfere with the proper functioning of the NPWT pump alarms.

Clinical Testing:

No clinical study was conducted.

Substantial Equivalence:

The FloSure Ventilation Patch is substantially equivalent in function and intended use to the UNI NPWT Foam Dressing Kit (K133333). Like the occlusive drape of the predicate UNI NPWT Foam Dressing Kit, the FloSure Ventilation Patch is semipermeable, maintains a moist environment for the wound by being hydrophobic, allows the exchange of gases, and maintains a protective barrier to the wound site. The FloSure Ventilation Patch performs the same basic function as the occlusive drape of NPWT Wound Dressing Kit. The support layer of the FloSure Ventilation Patch, which adheres to the NPWT occlusive drape, is composed of polyurethane, the same material that the occlusive drape is composed of. Performance testing with the predicate device and with the FloSure Ventilation Patch demonstrated that they were substantially equivalent in the ability to maintain consistent pressure, flow and removal of exudate when tested with the SIMEX EX^{200} and EX^{300} NPWT Systems.

Conclusion:

The FloSure Ventilation Patch is substantially equivalent to the currently marketed UNI NPWT Foam Wound Dressing Kits (K133333), in indications for use, basic technological characteristics, and does not raise new issues of safety and effectiveness.